

### **Remarks**

The various parts of the Office Action (and other matters, if any) are discussed below under appropriate headings.

#### ***Claim Rejections - 35 USC § 101***

Claims 22-25 stand rejected as being directed to non-statutory subject matter. The Examiner states that the device may not be positively recited relative to the bone. By way of the foregoing amendments, claim 22 has been amended to remove any issue as to the alleged non-statutory subject matter and therefore the rejection is now moot.

Accordingly, withdrawal of the rejection of claims 22-25 is respectfully requested.

#### ***Claim Rejections - 35 USC § 102 and § 103***

Claims 1-4, 6-16 and 22-25 as previously presented were rejected as being anticipated by or unpatentable over *Glossop* (US 6,203,543) and/or *Bramlet et al.* (US 6,183,474). Withdrawal of the art rejections is respectfully requested for at least the following reasons.

Independent claim 1 has been amended to clarify the orientation and relationship of the guide centerline and operative section center line. That is, the longitudinal centerline of the guide is offset from the longitudinal centerline of the operative section, whereby the securing element can be inserted into and moved axially along the guide into cooperative engagement with the object and the operative section to preclude rotation of the operative section. Similarly, amended claim 22 now refers to the groove extending parallel to a longitudinal axis of the operative section, with the longitudinal centerline of the groove being offset from a longitudinal centerline of the operative section.

#### ***Glossop***

Claims 1-4, 8-16 and 22-25 are rejected based on Fig. 1 of *Glossop*. With respect to Fig. 1 of *Glossop*, the Examiner identifies a distal portion of both elements 14

and 22 as the operative section, and a proximal portion 24 as the securing element. The Examiner also identifies a lumen within the sleeve 14 as the guide.

As can be seen in Fig. 1, a longitudinal centerline of the bone screw 12 and sleeve 14 (the alleged operative section), and a longitudinal center line of the threaded bore within the sleeve 14 (the alleged guide) are the same. Thus, Fig. 1 of *Glossop* does not teach or suggest that the alleged guide includes a longitudinal centerline that is offset from a longitudinal centerline of the alleged operative section. Similar arguments apply to claim 22.

Claims 2-4, 8-16 and 23-25 directly or indirectly depend from claim 1 or 22 and, therefore, can be distinguished from Fig.1 of *Glossop* for at least the same reasons.

Claims 1, 2, 6, 7 and 13-16 are rejected based on Fig. 2D of *Glossop*. With respect to Fig. 2D of *Glossop*, the Examiner identifies the lower portion of the bone screw 12 and the sleeve 14 as the operative section, and an upper portion 24 of the bone screw 12 as the securing element. With respect to the guide, the Examiner identifies two components that may be interpreted as a guide; a slot within clamp 20 and the lumen within sleeve 14.

Beginning with the interpretation that the threaded bore of the sleeve 14 is a guide, a longitudinal centerline of the bone screw 12 and sleeve 14 (the alleged operative section), and a longitudinal center line of the threaded bore of the sleeve 14 (the alleged guide) are the same. Thus, this interpretation of Fig. 2D does not teach or suggest that the alleged guide includes a longitudinal centerline that is offset from a longitudinal centerline of the alleged operative section.

Moving now to the interpretation that the slots within the clamp 20 are a guide, a longitudinal centerline of the bone screw 12 and sleeve 14 (the alleged operative section) and a longitudinal centerline of the leftmost slot (i.e., the slot surrounding the sleeve 14) of the clamp 20 are the same. Thus, interpreting the leftmost slot as the guide does not teach or suggest all the features of claim 1.

With respect to the rightmost slot (i.e., the slot within clamp 20 that holds the positioning element 8), the clamp 20 interfaces with an outer portion of the sleeve 14,

and not the upper portion 24 of the bone screw 12 (i.e., the alleged securing element). Thus, this interpretation does not teach *at least one guide for at least one securing element*, as recited in claim 1. Further, the alleged securing element (i.e., the upper portion 24 of the bone screw 12) and the alleged operative section (i.e., the lower portion of the bone screw 12 and the sleeve 14) include a common component (i.e., the bone screw 12). The whereby clause of claim 1 makes it clear the operative section and the securing element are different components.

Accordingly, Fig. 2D of *Glossop* also does not teach or suggest all the features of amended claim 1.

Claims 2, 6, 7 and 13-16 directly or indirectly depend from claim 1 and, therefore, can be distinguished from Fig. 2D of *Glossop* for at least the same reasons.

Accordingly, withdrawal of the rejections based on *Glossop* is respectfully requested.

### ***Bramlet***

Claim 22 stands rejected as being anticipated by *Bramlet*. The Examiner contends that *Bramlet* discloses an operative section 44 having external threads, and an axially extending groove comprising the proximal lumen of element 22, and a removable securing element 24.

Initially, it is noted that claim 22 recites a removable securing element for insertion along the axially extending groove of the operative section after the operative section has been inserted in the object, wherein when at least a portion of the securing element is in the groove, the securing element extends outwardly from the operative section and interacts with the object to fixedly retain the securing element in the object. The securing element 24 identified by the Examiner, however, does not extend outwardly from the operative section and interact with the object (e.g., the bone). Thus, the alleged securing element 24 of *Bramlet* does not teach all the features of claim 22.

Moreover, a longitudinal centerline of the alleged guide (i.e., the lumen within of element 22) and a longitudinal centerline of the alleged operative section 44 are the

same. Thus, *Bramlet* does not teach or suggest a guide includes a longitudinal centerline that is offset from a longitudinal centerline of the operative section.

Accordingly, withdrawal of the rejection of claim 22 based on *Bramlet* is respectfully requested.

***Conclusion***

In view of the foregoing, request is made for timely issuance of a notice of allowance.

Respectfully submitted,

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